

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

\_\_\_\_\_  
SANOFI-AVENTIS and )  
SANOFI-AVENTIS U.S. LLC, )  
 )  
Plaintiffs, )  
 )  
v. )  
 ) C.A. No. 1:07-cv-00572-GMS  
ACTAVIS SOUTH ATLANTIC LLC, )  
AUROBINDO PHARMA LTD., )  
AUROBINDO PHARMA USA INC., )  
MYLAN PHARMACEUTICALS INC., )  
PAR PHARMACEUTICAL, INC., )  
RANBAXY INC., RANBAXY )  
LABORATORIES LIMITED, SUN )  
PHARMACEUTICAL INDUSTRIES, )  
INC., SUN PHARMACEUTICAL )  
INDUSTRIES, LTD., TEVA )  
PHARMACEUTICALS USA, INC., )  
TORRENT PHARMA INC. and )  
TORRENT PHARMACEUTICALS )  
LIMITED )  
 )  
Defendants. )  
\_\_\_\_\_

**STIPULATION REGARDING AMENDMENT OF ANSWER AND  
COUNTERCLAIMS OF DEFENDANT ACTAVIS SOUTH ATLANTIC  
LLC TO PLAINTIFFS' COMPLAINT PURSUANT TO FED. R. CIV. P. 15(a)**

IT IS HEREBY STIPULATED AND AGREED, by and between counsel for the parties pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, that Defendant Actavis South Atlantic LLC (“Actavis”) may amend its Answer and Counterclaims to Plaintiffs’ Complaint in this action to correct typographical errors in the patent numbers cited in Paragraph 6 of the Counterclaims.

A copy of the First Amended Answer and Counterclaims of Defendant Actavis South Atlantic LLC to Plaintiffs’ Complaint (the “Amended Answer and Counterclaims”) \_\_\_\_\_

is attached hereto at Tab 1. A red-line version of the Amended Answer and Counterclaims is attached hereto at Tab 2.

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Dated: November 16, 2007

**CERTIFICATE OF SERVICE**

I, Dominick T. Gattuso, hereby certify that on November 16, 2007, I caused to be electronically filed a true and correct copy of the foregoing with the Clerk of the Court using CM/ECF that will send notification of such filing to the following counsel of record:

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# Exhibit

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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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SANOFI-AVENTIS and	)	C.A. No. 1:07-cv-00572-GMS
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)		C.A. No. 1:07-cv-00572-GMS
Plaintiffs,	)	
)		C.A. No. 1:07-cv-00572-GMS
v.	)	
ACTAVIS SOUTH ATLANTIC LLC,	)	C.A. No. 1:07-cv-00572-GMS
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MYLAN PHARMACEUTICALS INC.,	)	
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LABORATORIES LIMITED, SUN	)	
PHARMACEUTICAL INDUSTRIES,	)	
INC., SUN PHARMACEUTICAL	)	
INDUSTRIES, LTD., TEVA	)	
PHARMACEUTICALS USA, INC.,	)	
TORRENT PHARMA INC. and	)	
TORRENT PHARMACEUTICALS	)	
LIMITED	)	
)		
Defendants.	)	
)		

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**FIRST AMENDED ANSWER  
AND COUNTERCLAIMS OF DEFENDANT  
ACTAVIS SOUTH ATLANTIC LLC TO PLAINTIFFS' COMPLAINT**

Defendant Actavis South Atlantic LLC (“Actavis”) hereby responds to the corresponding paragraphs of the Complaint of the plaintiffs, sanofi-aventis and sanofi-aventis U.S. LLC (“sanofi-aventis U.S.”) as follows:

1. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 1 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

2. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

3. Actavis admits the allegations in Paragraph 3 of the Complaint.

4. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

5. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 5 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

6. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 6 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

7. Upon information and belief, Actavis admits the allegations in Paragraph 7 of the Complaint.

8. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 8 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

9. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 9 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

10. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 10 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

11. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 11 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

12. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 12 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

13. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 13 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

14. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 14 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

15. The allegations of Paragraph 15 of the Complaint set forth legal conclusions and characterizations. The Complaint speaks for itself, and no further response by Actavis is required, except to state that the Complaint purports to state a cause of action under Title 35 of the U.S. Code.

16. Actavis admits the allegations in Paragraph 16 of the Complaint.

17. Actavis denies the allegations in Paragraph 17 of the Complaint, except to state that it does not contest personal jurisdiction over itself in this proceeding.

18. Actavis admits the allegations in Paragraph 18 of the Complaint.

19. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 19 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

20. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 20 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

21. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 21 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

22. Upon information and belief, Actavis admits the allegations in Paragraph 22 of the Complaint.

23. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 23 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

24. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 24 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

25. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 25 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

26. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 26 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

27. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 27 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

28. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 28 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

29. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 29 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

30. Actavis admits the allegations in Paragraph 30 of the Complaint with respect to itself. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 30 of the Complaint with respect to any other defendant, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

31. Actavis admits that the ‘491 patent was issued by the United States Patent and Trademark Office (“PTO”) on April 28, 1987, that sanofi-aventis U.S. holds NDA No. 21-287 on Uroxtral® brand alfuzosin hydrochloride extended release tablets, and that the ‘491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) with respect to Uroxtral®. Actavis denies that the ‘491 patent was duly and legally issued by the PTO. Actavis has insufficient knowledge to admit or deny the remaining allegations, and therefore denies the same.

32. Actavis admits that the ‘940 patent was issued by the PTO on November 21, 2000, and that the ‘940 patent is listed in the Orange Book with respect to Uroxtral®. Actavis denies that the ‘940 patent was duly and legally issued by the PTO. Actavis has

insufficient knowledge to admit or deny the remaining allegations, and therefore denies the same.

33. Actavis admits the allegations in Paragraph 33 of the Complaint.
34. The statements made in Actavis' ANDA No. 79-055 speak for themselves and require no further response by Actavis. Actavis has insufficient knowledge to admit or deny the remaining allegations in Paragraph 34 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.
35. Actavis denies the allegations in Paragraph 35 of the Complaint.
36. Actavis denies the allegations in Paragraph 36 of the Complaint.
37. Actavis denies the allegations in Paragraph 37 of the Complaint.
38. Actavis denies the allegations in Paragraph 38 of the Complaint.
39. Actavis denies the allegations in Paragraph 39 of the Complaint.
40. Actavis admits the allegations in Paragraph 40 of the Complaint.
41. The statements made in Actavis' ANDA No. 79-055 speak for themselves and require no further response by Actavis. Actavis has insufficient knowledge to admit or deny the remaining allegations in Paragraph 41 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.
42. Actavis denies the allegations in Paragraph 42 of the Complaint.
43. Actavis denies the allegations in Paragraph 43 of the Complaint.
44. Actavis denies the allegations in Paragraph 44 of the Complaint.
45. Actavis denies the allegations in Paragraph 45 of the Complaint.
46. Actavis denies the allegations in Paragraph 46 of the Complaint.

47. – 108. Actavis has insufficient knowledge to respond to the allegations in Paragraphs 47 – 108 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

### **FIRST AFFIRMATIVE DEFENSE**

#### **Invalidity**

1. The '491 patent is invalid and unenforceable by reason of the failure of the '491 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

2. The '940 patent is invalid and unenforceable by reason of the failure of the '940 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

### **COUNTERCLAIMS**

#### **The Parties**

1. Actavis South Atlantic LLC ("Actavis") is a limited liability company established under the laws of Delaware, having a principal place of business at 13800 NW 2<sup>nd</sup> Street, Suite 190, Fort Lauderdale, Florida 33325.

2. Upon information and belief, sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

3. Upon information and belief, sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware, with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

**Declaration of Noninfringement and Invalidity**

4. Actavis repeats and realleges Paragraphs 1-3 of the counterclaims.

5. This claim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

6. In their Complaint, sanofi-aventis and sanofi-aventis U.S. assert that Actavis infringed United States Patent No. 4,661,491 (“the ‘491 patent”) and United States Patent No. 6,149,940 (“the ‘940 patent”) by submitting Abbreviated New Drug Application (“ANDA”) No. 79-055 including the § 505(j)(2)(A)(vii)(IV) allegations to the Food and Drug Administration (“FDA”), and that through ANDA No. 79-055 Actavis seeks FDA approval to manufacture and sell alfuzosin hydrochloride extended release tablets prior to the expiration of the ‘491 and ‘940 patents.

7. Actavis seeks a declaration that the ‘491 and ‘940 patents are not infringed and that the ‘491 and ‘940 patents are invalid.

8. The ‘491 patent was issued by the PTO on April 28, 1987, and currently names sanofi-aventis as the assignee of the named inventor Francois Regnier.

9. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that Actavis’ submission of ANDA No. 79-055 infringes the ‘491 patent under 35 U.S.C. § 271(e)(2)(A) and that Actavis’ commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would infringe the ‘491 patent. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that the ‘491 patent is valid.

10. Actavis' submission of ANDA No. 79-055 does not infringe the '491 patent under 35 U.S.C. § 271(e)(2)(A), and Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '491 patent.

11. The '491 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

12. The '940 patent was issued by the PTO on November 21, 2000, and currently names sanofi-aventis and Jagotec AG as the assignees of the named inventors Lauretta Maggi, Ubaldo Conte, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau, and Clemence Rauch-Desanti.

13. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that Actavis' submission of ANDA No. 79-055 infringes the '940 patent under 35 U.S.C. § 271(e)(2)(A) and that Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would infringe the '940 patent. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that the '940 patent is valid.

14. Actavis' submission of ANDA No. 79-055 does not infringe the '940 patent under 35 U.S.C. § 271(e)(2)(A), and Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '940 patent.

15. The '940 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

16. Actual and justiciable controversies exist between Actavis and sanofi-aventis/sanofi-aventis U.S. regarding the infringement and validity of the '491 and '940 patents.

17. Actavis is entitled to declarations that Actavis' submission of ANDA No. 79-055 does not infringe the '491 and '940 patents under 35 U.S.C. § 271(e)(2)(A) and that Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '491 and '940 patents.

18. Actavis is entitled to declarations that the '491 and '940 patents are invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Actavis demands judgment in its favor and against sanofi-aventis, and respectfully request that this Court:

- (a) Dismiss the Complaint with prejudice and deny each request for relief made by sanofi-aventis and sanofi-aventis U.S.;
- (b) Adjudge the claims of the '491 patent not infringed;
- (c) Adjudge the claims of the '940 patent not infringed;
- (d) Adjudge the claims of the '491 patent invalid;
- (e) Adjudge the claims of the '940 patent invalid;
- (f) Declare this case to be exceptional under 35 U.S.C. § 285;

- (g) Award Actavis its attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or general power of the Court;
- (h) Preliminarily and permanently enjoin sanofi-aventis and sanofi-aventis U.S., their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from utilizing the '491 patent to block, hamper, hinder or obstruct FDA approval of the product described in ANDA No. 79-055;
- (i) Preliminarily and permanently enjoin sanofi-aventis and sanofi-aventis U.S., their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from utilizing the '940 patent to block, hamper, hinder or obstruct FDA approval of the product described in ANDA No. 79-055;
- (j) Permanently enjoin sanofi-aventis and sanofi-aventis U.S., its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from asserting or otherwise seeking to enforce the '491 patent against Actavis or anyone in privity with Actavis;
- (k) Permanently enjoin sanofi-aventis and sanofi-aventis U.S., its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from asserting or otherwise seeking to enforce the '940 patent against Actavis or anyone in privity with Actavis; and
- (l) Award Actavis such other and further relief as the Court deems just and proper.

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Dated: November 16, 2007

**CERTIFICATE OF SERVICE**

I, Dominick T. Gattuso, hereby certify that on November 16, 2007, I caused to be electronically filed a true and correct copy of the First Amended Answer and Counterclaims with the Clerk of the Court using CM/ECF that will send notification of such filing to the following counsel of record:

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# Exhibit

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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and ) SANOFI-AVENTIS U.S. LLC, ) Plaintiffs, ) v. ) ACTAVIS SOUTH ATLANTIC LLC, ) AUROBINDO PHARMA LTD., ) AUROBINDO PHARMA USA INC., ) MYLAN PHARMACEUTICALS INC., ) PAR PHARMACEUTICAL, INC., ) RANBAXY INC., RANBAXY ) LABORATORIES LIMITED, SUN ) PHARMACEUTICAL INDUSTRIES, ) INC., SUN PHARMACEUTICAL ) INDUSTRIES, LTD., TEVA ) PHARMACEUTICALS USA, INC., _____ ) TORRENT PHARMA INC. and ) TORRENT PHARMACEUTICALS ) LIMITED ) Defendants. ) _____ )	) ) C.A. No. 1:07-cv-00572-GMS
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**FIRST AMENDED ANSWER  
AND COUNTERCLAIMS OF DEFENDANT  
ACTAVIS SOUTH ATLANTIC LLC TO PLAINTIFFS' COMPLAINT**

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Defendant Actavis South Atlantic LLC (“Actavis”) hereby responds to the corresponding paragraphs of the Complaint of the plaintiffs, sanofi-aventis and sanofi-aventis U.S. LLC (“sanofi-aventis U.S.”) as follows:

1. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 1 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

2. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

3. Actavis admits the allegations in Paragraph 3 of the Complaint.

4. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

5. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 5 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

6. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 6 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

7. Upon information and belief, Actavis admits the allegations in Paragraph 7 of the Complaint.

8. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 8 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

9. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 9 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

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10. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 10 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

11. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 11 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

12. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 12 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

13. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 13 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

14. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 14 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

15. The allegations of Paragraph 15 of the Complaint set forth legal conclusions and characterizations. The Complaint speaks for itself, and no further response by Actavis is required, except to state that the Complaint purports to state a cause of action under Title 35 of the U.S. Code.

16. Actavis admits the allegations in Paragraph 16 of the Complaint.

17. Actavis denies the allegations in Paragraph 17 of the Complaint, except to state that it does not contest personal jurisdiction over itself in this proceeding.

18. Actavis admits the allegations in Paragraph 18 of the Complaint.

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19. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 19 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

20. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 20 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

21. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 21 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

22. Upon information and belief, Actavis admits the allegations in Paragraph 22 of the Complaint.

23. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 23 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

24. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 24 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

25. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 25 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

26. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 26 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

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27. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 27 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

28. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 28 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

29. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 29 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

30. Actavis admits the allegations in Paragraph 30 of the Complaint with respect to itself. Actavis has insufficient knowledge to admit or deny the allegations in Paragraph 30 of the Complaint with respect to any other defendant, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

31. Actavis admits that the '491 patent was issued by the United States Patent and Trademark Office ("PTO") on April 28, 1987, that sanofi-aventis U.S. holds NDA No. 21-287 on Uroxtral® brand alfuzosin hydrochloride extended release tablets, and that the '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") with respect to Uroxtral®. Actavis denies that the '491 patent was duly and legally issued by the PTO. Actavis has insufficient knowledge to admit or deny the remaining allegations, and therefore denies the same.

32. Actavis admits that the '940 patent was issued by the PTO on November 21, 2000, and that the '940 patent is listed in the Orange Book with respect to Uroxtral®. Actavis denies that the '940 patent was duly and legally issued by the PTO. Actavis has

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insufficient knowledge to admit or deny the remaining allegations, and therefore denies the same.

33. Actavis admits the allegations in Paragraph 33 of the Complaint.

34. The statements made in Actavis' ANDA No. 79-055 speak for themselves and require no further response by Actavis. Actavis has insufficient knowledge to admit or deny the remaining allegations in Paragraph 34 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

35. Actavis denies the allegations in Paragraph 35 of the Complaint.

36. Actavis denies the allegations in Paragraph 36 of the Complaint.

37. Actavis denies the allegations in Paragraph 37 of the Complaint.

38. Actavis denies the allegations in Paragraph 38 of the Complaint.

39. Actavis denies the allegations in Paragraph 39 of the Complaint.

40. Actavis admits the allegations in Paragraph 40 of the Complaint.

41. The statements made in Actavis' ANDA No. 79-055 speak for themselves and require no further response by Actavis. Actavis has insufficient knowledge to admit or deny the remaining allegations in Paragraph 41 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

42. Actavis denies the allegations in Paragraph 42 of the Complaint.

43. Actavis denies the allegations in Paragraph 43 of the Complaint.

44. Actavis denies the allegations in Paragraph 44 of the Complaint.

45. Actavis denies the allegations in Paragraph 45 of the Complaint.

46. Actavis denies the allegations in Paragraph 46 of the Complaint.

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47. – 108. Actavis has insufficient knowledge to respond to the allegations in Paragraphs 47 – 108 of the Complaint, and leaves sanofi-aventis and sanofi-aventis U.S. to their proof.

**FIRST AFFIRMATIVE DEFENSE**

**Invalidity**

1. The '491 patent is invalid and unenforceable by reason of the failure of the '491 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

2. The '940 patent is invalid and unenforceable by reason of the failure of the '940 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

**COUNTERCLAIMS**

**The Parties**

1. Actavis South Atlantic LLC ("Actavis") is a limited liability company established under the laws of Delaware, having a principal place of business at 13800 NW 2<sup>nd</sup> Street, Suite 190, Fort Lauderdale, Florida 33325.

2. Upon information and belief, sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

3. Upon information and belief, sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware, with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

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**Declaration of Noninfringement and Invalidity**

4. Actavis repeats and realleges Paragraphs 1-3 of the counterclaims.

5. This claim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

6. In their Complaint, sanofi-aventis and sanofi-aventis U.S. assert that Actavis infringed United States Patent No. 4,661,491 ("the '491 patent") and United States Patent No. 6,149,940 ("the '940 patent") by submitting Abbreviated New Drug Application ("ANDA") No. 79-055 including the § 505(j)(2)(A)(vii)(IV) allegations to the Food and Drug Administration ("FDA"), and that through ANDA No. 79-055 Actavis seeks FDA approval to manufacture and sell alfuzosin hydrochloride extended release tablets prior to the expiration of the '491 and '940 patents.

**Deleted:** United States Patent No. 6,322,491 ("the '491 patent") and U.S. Patent No. 6,605,940 ("the '940 patent")

7. Actavis seeks a declaration that the '491 and '940 patents are not infringed and that the '491 and '940 patents are invalid.

8. The '491 patent was issued by the PTO on April 28, 1987, and currently names sanofi-aventis as the assignee of the named inventor Francois Regnier.

9. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that Actavis' submission of ANDA No. 79-055 infringes the '491 patent under 35 U.S.C. § 271(e)(2)(A) and that Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would infringe the '491 patent. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that the '491 patent is valid.

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10. Actavis' submission of ANDA No. 79-055 does not infringe the '491 patent under 35 U.S.C. § 271(e)(2)(A), and Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '491 patent.

11. The '491 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

12. The '940 patent was issued by the PTO on November 21, 2000, and currently names sanofi-aventis and Jagotec AG as the assignees of the named inventors Lauretta Maggi, Ubaldo Conte, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau, and Clemence Rauch-Desanti.

13. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that Actavis' submission of ANDA No. 79-055 infringes the '940 patent under 35 U.S.C. § 271(e)(2)(A) and that Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would infringe the '940 patent. In their Complaint, sanofi-aventis and sanofi-aventis U.S. maintain, and Actavis denies, that the '940 patent is valid.

14. Actavis' submission of ANDA No. 79-055 does not infringe the '940 patent under 35 U.S.C. § 271(e)(2)(A), and Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '940 patent.

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15. The '940 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103 and 112.

16. Actual and justiciable controversies exist between Actavis and sanofi-aventis/sanofi-aventis U.S. regarding the infringement and validity of the '491 and '940 patents.

17. Actavis is entitled to declarations that Actavis' submission of ANDA No. 79-055 does not infringe the '491 and '940 patents under 35 U.S.C. § 271(e)(2)(A) and that Actavis' commercial use, offer for sale or sale of its alfuzosin hydrochloride extended release tablets would not infringe the '491 and '940 patents.

18. Actavis is entitled to declarations that the '491 and '940 patents are invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Actavis demands judgment in its favor and against sanofi-aventis, and respectfully request that this Court:

- (a) Dismiss the Complaint with prejudice and deny each request for relief made by sanofi-aventis and sanofi-aventis U.S.;
- (b) Adjudge the claims of the '491 patent not infringed;
- (c) Adjudge the claims of the '940 patent not infringed;
- (d) Adjudge the claims of the '491 patent invalid;
- (e) Adjudge the claims of the '940 patent invalid;
- (f) Declare this case to be exceptional under 35 U.S.C. § 285;

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- (g) Award Actavis its attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or general power of the Court;
- (h) Preliminarily and permanently enjoin sanofi-aventis and sanofi-aventis U.S., their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from utilizing the '491 patent to block, hamper, hinder or obstruct FDA approval of the product described in ANDA No. 79-055;
- (i) Preliminarily and permanently enjoin sanofi-aventis and sanofi-aventis U.S., their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from utilizing the '940 patent to block, hamper, hinder or obstruct FDA approval of the product described in ANDA No. 79-055;
- (j) Permanently enjoin sanofi-aventis and sanofi-aventis U.S., its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from asserting or otherwise seeking to enforce the '491 patent against Actavis or anyone in privity with Actavis;
- (k) Permanently enjoin sanofi-aventis and sanofi-aventis U.S., its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with sanofi-aventis and/or sanofi-aventis U.S., from asserting or otherwise seeking to enforce the '940 patent against Actavis or anyone in privity with Actavis; and
- (l) Award Actavis such other and further relief as the Court deems just and proper.

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Dated: November 16, 2007

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**CERTIFICATE OF SERVICE**

I, Dominick T. Gattuso, hereby certify that on November 16, 2007, I caused to be electronically filed a true and correct copy of the First Amended Answer and Counterclaims with the Clerk of the Court using CM/ECF that will send notification of such filing to the following counsel of record:

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I further certify that on November 16, 2007, I caused copies of the foregoing document to be served by e-mail on the following.

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